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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/188,051	11/06/1998	BRET A. SHIRLEY	5784-25	3829

7590                    05/31/2002

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[REDACTED] EXAMINER

KAM, CHIH MIN

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1653

DATE MAILED: 05/31/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application N .</b>	<b>Applicant(s)</b>
	09/188,051	SHIRLEY ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Chih-Min Kam	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 February 2002.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 29-48 and 85-112 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 29-48 and 85-112 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***Oath/Declaration***

1. The Oath/Declaration is defective because it indicates that the instant application claims the benefit of a provisional application serial no. 60/064,891, filed 11/07/97 under 35 U. S. C. §120, which is not correct, the instant application should claim the benefit of of a provisional application under 35 U. S. C. §119(e).

### ***Status of the Claims***

2. Claims 29-48 and 85-112 are pending.

Applicants' amendment filed on February 21, 2002 (Paper No. 24) is acknowledged, and applicants' response has been fully considered. Claims 31 and 46 have been amended.

### **Rejection Withdrawn**

#### ***Claim Rejections - 35 USC § 112***

3. The previous rejection of claims 29-48 and 85-112 under 35 U.S.C. 112 first paragraph, is withdrawn in view of applicants' response at pages 3-6 (Paper No. 24).

4. The previous rejection of claims 29-48 and 85-112 under 35 U.S.C. 112 second paragraph, regarding the term "at least 70% sequence identity", "biologically active analogue", "IGF-I or analogue", "in an amount sufficient to make IGF-I or analogue thereof soluble" or "at least 95% sequence identity" is withdrawn in view of applicants' amendment to the claim and applicants' response at pages 7-9 in Paper No. 24.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 29-48 and 85-112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29-48 and 85-112 are indefinite because of the use of the term “at least about pH 5.5” or “at least about 12 mg”. The term “at least about pH 5.5” or “at least about 12 mg” renders the claim indefinite; it is unclear what pH the composition has, it appears that the composition can have a pH greater than 5.5 as to “at least”, but it can also have a pH less than 5.5 as to “about”; and at what concentration IGF-I or IGF-I analog is present in the composition, e.g., IGF-I or IGF-I analog can be greater than 12 mg as to “at least”, but it can also be less than 12 mg as to “about”. Claims 30-45, 47-48, 86-98, 100 and 102-112 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

In response, applicants indicate the term “at least about” is definite, and the word “about” is often used in claims to avoid literal infringement by making minor modification. The argument is not found persuasive because the term, e.g., “at least about pH 5.5” indicates the pH can be greater than 5.5 as to “at least” or less than 5.5 as to “about” as discussed above.

6. Claim 35, for example, is indefinite because of the use of the term “from about.... to about...”. The term “from about.... to about...” renders the claim indefinite, it is unclear whether the concentration of arginine is in the range of 10 mM - 1 M as to “from ....to...” or outside the range as to “about”. See also claims 36-39, 88-92, and 102-106. Use of the term “from...to...” or “about ....to..” is suggested.

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In response, applicants indicate the term “from about.... to about...” is definite, and it is the same as suggested by the Examiner. The argument is not found persuasive because the term, e.g., “from about 10 mM to about 1 M” can mean the concentration is in the range of 10 mM - 1 M or outside the range as discussed above.

***Conclusion***

7. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.

CMK

Patent Examiner

*Karen Cochrane Carlson Ph.D.*  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER

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May 24, 2002